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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,965	SOLOM, WARREN	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-95 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 20 December 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/1/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner has noted the existence of several claimed species (e.g., the species wherein the insulating layer is formed on just an interior surface, the species wherein the insulating layer is formed on just an exterior surface, the species wherein the insulating layer is formed on a combination of interior and exterior surfaces, the species wherein the insulating layer is an oxide, the species wherein the insulating layer is a ceramic material, the species wherein the insulating layer is an epoxy material, the species wherein the insulating layer is a plastic, etc., the species wherein the case metal is aluminum, the species wherein the case metal is titanium, the species wherein the case metal is stainless steel) but has not required an election of species because the listed species are not considered to be patentably distinct.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiment wherein the insulating coating is on both the interior and exterior surfaces of any one element (see for example claims 21, 22, etc.) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the

appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 86 is objected to because of the following informalities: the reference to *interior surfaces* on line 2 lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 is confusing. The claim refers to "...said insulating material formed on said at least one interior surface of said component case," yet the insulating material in parent claim 26 is only recited as being formed on an exterior surface with no mention

of interior surfaces. The examiner will assume that the insulating material is on the exterior surface in any rejection on the merits.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 83-85, 87, 91 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bardy (Pat. No. 5,261,400).

9. Claims 83-85, 87, 93, 94 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Purdy (Pat. No. 3,866,616).

10. Claims 1, 2, 15, 51, 56, 62, 83, 84, 92 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ware (Pat. No. 4,243,042).

11. Claims 1-4, 7, 14, 15, 18, 51, 55, 56, 59, 61, 62, 83-86, 91, 92 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahlberg (Pat. No. 5,769,874).

Regarding claim 1, Dahlberg discloses a device housing 211 having a plurality of interior surfaces, a component case 212 positioned within said device housing, and having a plurality of interior surfaces, and an insulating material 213 formed on at least one of said plurality of interior surfaces of at least one of said device housing and said component case.

By definition, a case can be reasonably defined as "...a protective cover or covering part..." (Webster's New World Dictionary, Third College Edition 1988). Since

the applicant has not explicitly defined the term with reasonable clarity, deliberateness and precision, the term "case" will be interpreted in its broadest reasonable sense. Element 212 is therefore considered to represent a protective cover or covering part since it protects or covers the battery component, and thus is by definition a case.

Concerning the issue of the case having a plurality of interior surfaces, since the applicant has not defined what an interior surface constitutes, one can reasonably consider any surface of the case 212 to be interior with respect to the device housing (e.g., both the top surface of the case and the bottom surface of the case are interior surfaces since they are inside the housing).

Regarding claim 51, Dahlberg discloses providing a device housing 211 having a plurality of interior surfaces and forming an insulating material 213 on the interior surface of the device housing (see Fig. 2). The limitation stating that one provides *at least one of* a device housing and a component case can be met by any reference that discloses one or the other. In any event, Dahlberg discloses both a housing 211 and a component case (defined by elements 211 and 212). The disclosure that the case may be integrated with a section of the housing does not negate the fact that a housing and a component case exist. The component case with battery shown in Fig. 1, for example, must necessarily be associated with a device housing containing an electronics module.

Regarding claim 86, the examiner considers Fig. 1 to show a device housing containing a battery, wherein insulating material 113 is formed on all interior surfaces.

12. Claims 1, 6, 14, 15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kenny (Pat. No. 4,248,237).

Kenny discloses a device housing 40 having a plurality of interior surfaces, a component case positioned within the device housing (note electronics package 47 and battery pack 49, with the 3-dimensional component packages or cases inherently having a plurality of interior surfaces). An insulating material (41, 42 and/or 52) is formed on at least one of said plurality of interior surfaces as shown by Fig. 9.

Regarding claim 6, the examiner considers elements 41 and 42 to cover the entire interior surface of housing 53. One can also consider element 52 to cover the entire interior surface of the housing made up of elements 53, 41 and 42.

Regarding claim 19, note element 51 of Fig. 8.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-5, 10, 14, 15, 18, 51, 54-56, 59, 62, 83-86, 89, 91, 92 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlberg (Pat. No. 5,769,874) in view of Pless et al. (Pat. No. 5,131,388).

Dahlberg discloses an implantable medical device comprising a component case (111, 112) with a plurality of interior surfaces and an insulating material 113 formed on

at least one of the interior surfaces. Although a device housing is not shown in the embodiment of Fig. 1, clearly it was the intent of Dahlberg to include such structure. A housing for containing the disclosed battery and associated electronic circuitry would have been considered a necessity for any practical medical implant. Dahlberg in fact teach that in a second embodiment shown in Fig. 2, additional encapsulation of the battery is not needed (col. 3, lines 35-43). Such a statement implies that the embodiment of Fig. 1 requires additional encapsulation of the battery. Pless et al. disclose a similar implantable device wherein a battery case 78 is employed to house the battery (while element 78 is merely referred to as the battery, clearly a battery case is required to hold the battery chemistry as taught by Dahlberg in col. 1, lines 27-32). Such a system enhances the biocompatibility and safety of medical implants by adding a further layer of protection. To incorporate the component case of Dahlberg within a device housing would have therefore been considered a matter of obvious design by artisans of ordinary skill in the medical implant arts.

Regarding claim 10, Dahlberg does not discuss insulating material thickness. Considering that both Dahlberg and the applicant employ their coatings on similar components for similar reasons, one would expect routine experimentation to decide the exact dimension of insulator thickness. Such a measure would obviously depend upon battery chemistry and insulating material chosen. Those of ordinary skill in the art would have therefore considered the range of thicknesses presented in claim 10 to be a matter of obvious design. It should be noted that Pless et al. describe a solvent resistant polymeric envelope for containing the capacitor that is described as having a

thickness of between 10 nm and 500 micrometers (note col. 3, lines 53-56). A related comment applies to claims 54 and 89.

15. Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny (Pat. No. 4,248,237) in view of Dahlberg.

Kenny does not discuss details associated with the component cases 47 and 49. Dahlberg, however, teaches that a battery casing such as shown by Kenny, can benefit by the provision of a layer of insulating material (see Fig. 1). Such a layer makes the encapsulation essentially impermeable to battery chemicals, thus preventing hazardous leaks that can damage other circuitry and/or harm the patient. Given the teachings of Dahlberg, any artisan desiring a better battery casing to enhance device longevity, would have therefore seen the obviousness of incorporating an insulating layer on the interior surface of the component case.

16. Claims 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlberg (Pat. No. 5,769,874) in view of Pless et al. (Pat. No. 5,131,388) as applied to claims 1-5, 10, 14, 15, 18, 51, 54-56, 59, 62, 83-86, 89, 91, 92 and 95 above, and further in view of Czura et al. (Pat. No. 5,562,715).

Regarding claim 21, Dahlberg does not discuss the use of an insulating material formed on at least one of the exterior surfaces of the housing. Czura et al., however, teach that such an arrangement is beneficial from a number of standpoints including corrosion resistance and preventing unwanted pectoral twitching. To incorporate an insulating material on the exterior of a housing would have therefore been considered

obvious by those of ordinary skill in the art wishing to take advantage of such a beneficial arrangement.

17. Claims 26-28, 31, 34-43, 67-76, 78, 83-85 and 87-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless et al. (Pat. No. 5,131,388) in view of Czura et al. (Pat. No. 5,562,715).

Regarding claim 26, Dahlberg does not discuss the use of an insulating material formed on at least one of the exterior surfaces of the housing. Czura et al., however, teach that such an arrangement is beneficial from a number of standpoints including corrosion resistance and preventing unwanted pectoral twitching. To incorporate an insulating material on the exterior of any medical device housing would have therefore been considered obvious by those of ordinary skill in the art wishing to take advantage of such a beneficial arrangement.

Regarding claims 34, 36-43 and claims of a similar nature, as stated above in paragraph 1, the various insulating material species and housing metal species were not considered to be patentably distinct. Any biocompatible insulating material suitable to the task would have been considered obvious to apply by those of ordinary skill in the art. Attention is invited to col. 4, lines 4-11 of Czura et al.. Clearly metal oxides, epoxies, plastics and ceramics have been used for this purpose and are highly compatible with the body.

Regarding claim 35, the particular thickness of insulating material on the device housing clearly would depend upon routine experimentation to best determine the most

appropriate and effective dimension. Those of ordinary skill in the art would have therefore seen the provision of a coating in the recited range as obvious.

18. Claims 1-3, 5, 6, 9-40, 44-46, 51-60, 62-70 and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latterell et al. (Pat. No. 5,814,090).

Regarding claim 1, Latterell et al. disclose a housing 10 with a plurality of interior surfaces with an insulating material (see Fig. 4) formed at least on one of the plurality of interior surfaces of at least one of the housing and component case. Although Latterell et al. do not appear to explicitly refer to the use of a component case, the examiner takes Official Notice that component cases to contain medical implant batteries, capacitors, etc., are old and well known to those of ordinary skill in the art. Such cases are needed to protect the circuitry both inside the case and outside the case due to such caustic elements as battery chemicals and the like.

Regarding claim 9, the use of metal oxides as insulating materials on medical implants is old and well known. Such materials are biocompatible and serve to adequately insulate the medical device from its environment. To select a known material dependent upon its suitability to perform the required task has been considered obvious by the courts (see MPEP 2144.07).

Regarding claim 10, note col. 6, lines 61, etc.. Note also the comments made above in the rejection of claim 10 under other prior art. The same reasoning applies here.

Regarding claims directed to the use of different metals, metal oxides, epoxies and ceramics, again note the comments made above in the rejection of like claims as similar reasoning applies here.

Regarding claims 22-24, Latterell et al. disclose that insulating material may be formed on the exterior surfaces of components (see Figs. 6-8).

Regarding claim 25 and claims with similar limitations, the examiner considers it inherent that titanium oxide will form on the outer hull of the titanium housing when exposed to the air. In any event, the use of insulating materials on the exteriors of medical device housings is old and well known in the art. Official Notice is given.

Concerning claim 29, the examiner takes Official Notice that aluminum, titanium and stainless steel component cases are old and well known in the prior art.

Regarding claim 44, the examiner considers Figs. 6-8 of Latterell et al. to show an insulating liner positioned between the components with the insulating liner material on the exterior of the component case.

19. Claims 47-50, 61, 77 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latterel et al. as applied to claims 1-3, 5, 6, 9-40, 44-46, 51-60, 62-70 and 77-81 above, and further in view of Dahlberg.

Latterel et al. do not discuss applying an insulating material on at least one the interior surfaces of the component case. Dahlberg discloses an implantable medical device comprising a component case (111, 112) with a plurality of interior surfaces and an insulating material 113 formed on at least one of the interior surfaces. Such a layer of insulation protects the delicate electronics of the medical device by preventing

corrosion. The applicant gives no criticality as to how many layers of insulating material are incorporated into the medical device. Any one desiring maximum protection would have seen the incorporation of such a protective layer as obvious. The examiner further did not consider the various embodiments concerning the placement of the insulating layer to be patentably distinct. Whether one places the insulation inside the component casing, outside the component casing, on the inside surface of the housing, outside the housing or any combination thereof would have been considered a matter of obvious design by those of ordinary skill in the art.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
June 14, 2004

KENNEDY SCHAETZLE
PRIMARY EXAMINER